Title 21 Vacancy Announcement
U.S. Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Office of New Drugs (OND)
Immediate Office (IO)

Application Period: October 13, 2023 - October 27, 2023

Area of Consideration: United States Citizenship is required. You must be a U.S. Citizen or U.S. National. Foreign nationals or legal permanent residents are not eligible for consideration.

Position: Deputy Super Office Director (Supervisory Physician)

Series: AD-0602

Location(s): Silver Spring, MD

Salary: Starting at $210,000

Work Schedule: Full Time

Cures Band(s): Band F

Full Performance Band Level: Band F

Travel Requirements: 25% or less

Bargaining Unit: 8888

Relocation Expenses Reimbursement: You may qualify for reimbursement of relocation expenses in accordance with agency policy.

This position is being filled under a stream-lined hiring authority, Title 21, Section 3072 of the 21st Century Cures Act. The candidate selected for this position will serve under a career or career-conditional appointment and be paid under the provisions of this authority. Additional information on 21st Century Cures Act can be found here:
21st Century Cures Act Information

Introduction

The Food and Drug Administration (FDA) is the regulatory, scientific, public health and consumer protection agency responsible for ensuring all human and animal drugs, medical devices, cosmetics, foods, food additives, drugs and medicated feeds for food producing animals, tobacco and radiation emitting devices safe, and effective.

The mission of the Center for Drug Evaluation and Research (CDER) is to perform an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. CDER regulates over the counter and prescription drugs,

including biological therapeutics and generic drugs.

The Office of New Drugs (OND) is a dynamic, purpose-driven organization dedicated to the review of new drug applications (NDAs), interactions with the pharmaceutical industry and ultimately deciding whether the benefits of a drug outweigh the known risks. OND is a multi-disciplinary organization engaged in the oversight of human drug trials in the United States, in review of NDAs and biologics license applications (BLAs) for marketing drugs and therapeutic biologics in this country, and in regulating over-the-counter (OTC) drug products.

The Immediate Office (IO) provides clinical, nonclinical, and regulatory expertise on the full range of drugs and therapeutic biologics that can be made available to the American people.

Duties/Responsibilities

The incumbent serves as the **Deputy Director for Analgesics**, **Controlled Substances and Substance Use Disorders** within the Office of New Drugs (OND). Responsible for coordinating, providing input, and direction on efforts and regulatory programs within OND on programs directed towards analgesia drug development, controlled substances, and disorders related to their use, including treatments for the range of substance use disorders (SUD) and development of overdose reversal agents regulated within OND.

The incumbent will have direct Office-level technical authority and will coordinate and provide input across OND on all relevant programs on SUD and related reversal agents. Serves a key role in supporting and leading efforts in OND for policy development (e.g., guidance development) on the treatment and management of substance use disorders, development of medications for pain management, and reversal agents related to controlled substances. This incumbent will also perform the following duties:

- Serves as a liaison to CDER and FDA efforts on analgesic drug development, substance use disorders and controlled substance programs and policies, as well as serving as a key OND representative to external groups (e.g., patient stakeholders, academic groups, other governmental organizations, industry) that are engaged in development of treatments for pain, for SUD, and policy development regarding controlled substances.
- Coordinates and provides office-level guidance to OND office and divisional leadership on development programs focused on controlled substances and analgesic drug development.
- Provides leadership for policy development related to analgesic drug development, controlled substances, SUD or overdose reversal treatments in coordination with OND policy.
- Serves as the point person to assure OND delivery of relevant agency priorities on controlled substances in conjunction with CSS and CDER staff.
- Acts as liaison with other government agency groups involved in policy development on analgesic drug development, controlled substances, SUD, and overdose reversal such as

working with National Institutes of Health (NIH), National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Drug Abuse (NIDA), Department of Defense (DoD) and other relevant organizations
- Coordinates OND research efforts focused on analgesic drug development, controlled substances, SUD or OD reversal agents. Coordinates with legislative affairs (Office of Legislation in CDER) to respond to inquiries on activities for analgesics, controlled substances, SUD and overdose prevention and management.

Supervisory Responsibilities: Manages one or more portfolios and provides leadership and direction for multiple, smaller program offices in coordination with the Super Office Director. Provides occupational specific technical and administrative direction and supervision 25 percent or more of the time to subordinate staff (including supervisors and team leads if appropriate) performing the work and functions of the organizational unit.

Conditions of Employment

- U.S. Citizenship requirement or proof of being a U.S. National must be met by closing date.
- Employment is subject to the successful completion of a background investigation, verification of qualifications, completion of onboarding forms, submission of required documents, and any other job-related requirement before or after appointment.
- Applicants must meet all qualification requirements by the closing date of this announcement.
- Direct Deposit: You will be required to have all federal salary payments electronically deposited into a bank account with a financial institution of your choice.
- FDA participates in e-Verify: All new hires must complete the I-9 form; this information will be processed through e-Verify to determine your employment eligibility. If a discrepancy arises, you must take affirmative steps to resolve the matter.
- Males born after December 31, 1959 must be registered with the Selective Service.
- One-year supervisory probationary period may be required.
- Financial Disclosure may be required.
- Ethics Clearance may be required.
- Background Investigation/Security Clearance is required. All employees must pass a security investigation. Failing to pass the background check may be grounds for removal or legal action. If hired, you may be subject to additional investigations at a later time.

Qualifications

To be placed into a Cures position, candidates must meet the following criteria:

1. Scientific, Technical, and Professional Fields
2. Qualified and Outstanding Candidates
    a. ***Qualified*** applies to all candidates for Cures appointments. The FDA OTS will use the basic requirements defined in the OPM Qualification Standards as a baseline for comparing experience levels and other candidate attributes for relevant positions.

b. ***Outstanding*** candidates can be defined by existing outstanding work experience, outstanding performance rating, or both.

To qualify for this Title 21 Cures position, the candidate(s) must meet the following **required** qualifications. *Please note: Additional education and experience listed that is not indicated as required is preferable and desired. Candidates who do not meet the "desired" criteria will not be excluded from consideration for this position.*

Education Requirement:

Physician Series, AD- 0602:

Degree from Foreign Medical School: A Doctor of Medicine or equivalent degree from a foreign medical school must provide education and medical knowledge equivalent to accredited schools in the United States. Evidence of equivalency to accredited schools in the United States is demonstrated by permanent certification by the Educational Commission for Foreign Medical Graduates, a fifth pathway certificate for Americans who completed premedical education in the United States and graduate education in a foreign country, or successful completion of the U.S. Medical Licensing Examination.

For more information, please see: OPM Occupational Series Qualification Requirements.

Desired Education:
Our ideal candidate will possess advanced post-graduate training in specialties relevant to analgesic drug development, SUD (e.g., extensive experience in, and/or residency in psychiatry, neurology, or post-residency fellowship training in addiction medicine or related fellowship training) or having completed a residency in internal medicine.

Desired Professional Experience:
Our ideal candidate will possess:

- Direct clinical experience in the management of patients with pain disorders and/or SUD.
- Experience in drug development to include participation in design and conduct of relevant clinical trials.
- Experience in development of analgesic drugs and/or drugs for treatment of SUD.
- Experience in policy development, program development, and coordination of efforts in pain management, and/or the treatment of SUD, and/or policies and programs related to controlled substances.
- Ability to apply knowledge of regulatory environments related to the regulation of drugs and related policy.
- Ability to apply knowledge of leadership principles and concepts regulating and evaluating new drugs and biological products.

- Ability to drive collaboration, empower staff, provide expert advice and consultation, coordinate program activities and spearhead important program initiatives.

Education Transcripts

SUBMITTING YOUR TRANSCRIPTS: Positions which are scientific or technical in nature often have very specific educational requirements. A transcript is required to verify educational achievement. Pay careful attention to the Qualifications and Education sections to identify vacancies where a transcript is required. Even if you hold a similar position or are a current FDA employee, you are not exempt from transcript requirements.

FOREIGN EDUCATION: If you are using education completed in foreign colleges or universities to meet the qualification requirements, you must show that the education credentials have been evaluated by a private organization that specializes in interpretation of foreign education programs and such education has been deemed equivalent to that gained in an accredited U.S. education program; or full credit has been given for the courses at a U.S. accredited college or university. For more information about this requirement, please visit the U.S. Department of Education website for Foreign Education Evaluation.

Security Clearance Requirements

Background Investigation/Security Clearance Requirements: Non-Sensitive/High Risk

A background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet the requirements may be grounds for appropriate personnel action. In addition, if hired, a background security investigation or supplemental investigation may be required later.

Applicants are also advised that all information concerning qualification is subject to investigation. False representation may be grounds for non-selection and/or appropriate disciplinary action.

Ethics Clearance Requirements

This position may require financial disclosure reporting and will be subject to FDA's prohibited financial interest regulation. If you are hired, you may be required to divest of certain financial interests. You are advised to seek additional information on this requirement from the hiring official before accepting any job offers. For more information, please visit the FDA Ethics web page: https://www.fda.gov/about-fda/jobs-and-training-fda/ethics.

Equal Employment Opportunity

Equal Employment Opportunity Policy

The United States Government does not discriminate in employment on the basis of race, color, religion, sex (including pregnancy and gender identity), national origin, political affiliation,

sexual orientation, marital status, disability, genetic information, age, membership in an employee organization, retaliation, parental status, military service, or other non-merit factor. Equal Employment Opportunity (EEO) for federal employees & job applicants

Reasonable Accommodation

Reasonable Accommodation Policy

Federal agencies must provide reasonable accommodation to applicants with disabilities where appropriate. Applicants requiring reasonable accommodation for any part of the application process should follow the instructions in the job opportunity announcement. For any part of the remaining hiring process, applicants should contact the hiring agency directly. Determinations on requests for reasonable accommodation will be made on a case-by-case basis. A reasonable accommodation is any change to a job, the work environment, or the way things are usually done that enables an individual with a disability to apply for a job, perform job duties or receive equal access to job benefits.

Under the Rehabilitation Act of 1973, federal agencies must provide reasonable accommodations when: An applicant with a disability needs an accommodation to have an equal opportunity to apply for a job. An employee with a disability needs an accommodation to perform the essential job duties or to gain access to the workplace. An employee with a disability needs an accommodation to receive equal access to benefits, such as details, training, and office-sponsored events. You can request a reasonable accommodation at any time during the application or hiring process or while on the job. Requests are considered on a case-by-case basis. Learn more about disability employment and reasonable accommodations or how to contact an agency.

E-Verify

The Food and Drug Administration participates in the USCIS Electronic Employment Eligibility Verification Program (E-Verify). E-Verify helps employers determine employment eligibility of new hires and the validity of their Social Security numbers.

How to Apply

Submit resume or curriculum vitae with unofficial transcripts by **October 27, 2023,** to Karen Koenick at CDER-OND-Leadership-Employment@fda.hhs.gov. Candidate resumes may be shared with hiring officials within the Center for Drug Evaluation and Research with a similar job vacancy. Candidates can opt out of this process by annotating resume with “do not share”.

Please reference **Job Reference ID: IO-23-048** in the email subject line.

Announcement Contact

For questions regarding this Cures position, please contact Karen Koenick at Karen.Koenick@fda.hhs.gov

smoke free environment.

FDA is an equal opportunity employer.